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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/618,570 | 07/11/2003 | Seppo Yla-Herttula | GJE-48D1 | 3776 |
| 23557 | 7590 | 02/28/2006 | EXAMINER | |
| SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950 | | | LI, RUIXIANG | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1646 | | |

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------|----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/618,570 | YLA-HERTTUALA ET AL. | |
| | Examiner Ruixiang Li | Art Unit 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 2/3/2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 16 and 17 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 12-15 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 22 December 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 09/622,804.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 04/23/2004.
 - 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 - 5) Notice of Informal Patent Application (PTO-152)
 - 6) Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicants' election without traverse of Group II (claims 12-15) in the reply filed on 02/03/2006 is acknowledged. Applicants' preliminary amendment filed on 07/11/2003 has been entered. Claims 1-17 are pending. Claims 12-15 are under consideration. All other claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

2. The information disclosure statement filed on 04/23/2004 has been considered and a signed copy has been attached to the office action.

Drawings

3. The drawings filed on 12/23/2003 are accepted by the Examiner.

Claim Rejections —35 U.S.C.§ 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 12 and 13 are rejected under 35 U.S.C. 101 because the claimed invention is directed non-statutory subject matter.

Claims 12 and 13, as written, do not sufficiently distinguish over a nucleic acid molecule that exists naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring product. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" or "purified" as taught by the specification. See MPEP 2105.

Claim Rejections—35 USC §112, 2nd paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The non-elected claim 1, to which claims 12-15 depend from, is indefinite because it recites "wherein the extracellular domain comprises biotin-binding activity". It is understood in the art that an extracellular domain comprises an amino acid sequence or a specific structure, not a specific activity. It is suggested that the claim be amended to recite "wherein the extracellular domain binds biotin".

Claim Rejections—35 USC § 102 (b)

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Cantor et al. (WO 87/05026, August 27, 1987).

Cantor et al. teach a fusion protein comprising streptavidin and human LDL receptor (see Example 2): streptavidin at the N-terminal region and the LDL receptor at the C-terminal region of the fusion protein (first paragraph of page 28). The region of the LDL receptor gene used in the fusion is the region that encodes for 159 amino acids of the C-terminal region of the protein. In the native receptor this region comprises a short extracellular tail (88 amino acids), the membrane-spanning region (22 amino acids), and the intracellular domain (49 amino acids) (the 2nd paragraph of page 28). Cantor et al. also a nucleic acid molecule encoding the fusion protein, a recombinant expression vector, and a process for production of the fusion protein (Example 2 and claims 25, 31, 32, and 45). Thus, the teachings of Cantor et al. meet the limitations of claims 12-15.

Claim Objections—Minor Informalities

10. Claims 12-15 are objected to because they depend on non-elected claim 1. Appropriate correction is required.

11. Claim 15 is objected to under 37 CFR 1.75(c) as being in improper form because it depends upon both claims 1 and 14. A multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

Conclusion

12. No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Primary Examiner
February 24, 2006

RUIXIANG LI, PH.D.
PRIMARY EXAMINER